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CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 26 March 2003 with an application for Letters Patent number 524982 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 6 January 2004.

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NEW ZEALAND

PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

"Mouthpiece"

We, FISHER & PAYKEL HEALTHCARE LIMITED, a company duly incorporated under the laws of New Zealand, of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

BACKGROUND OF THE INVENTION

Field of Invention

This invention relates to a system for oral delivery of gases pressurized above ambient, and in particular, to a system, including a novel mouthpiece, for the oral delivery of air or gases in continuous positive airway pressure (CPAP) treatments of sleeping disorders such as sleep apnoea.

Description of the Prior Art

Sleep apnoea treatments have been significantly advanced with the introduction of continuous positive airway pressure (CPAP) treatments. These treatments, as introduced, involve the supply of gases from a gases supply or blower to a patient or user through a conduit and nasal mask to provide an elevated internal pressure in the user's airways to assist the muscles to keep the airways open. This airstream is provided to the user through a nasal mask applied over the nose and held in place by a harness. This configuration has been almost universally adopted based on the well-known observation that humans show a decided preference for nasal breathing during sleep. For this reason, little development has been undertaken into other possible methods of providing the pressurized airstream to a user.

Oral delivery is suggested in EP818213, which shows an apparatus for oral delivery of air in a CPAP treatment. The apparatus includes a mouthpiece adapted to fit inside the mouth between the roof of the mouth, the hard palate, and the tongue, and having a periphery that can be gripped between the teeth. It is thought by the applicants that this is significantly more intrusive than is necessary and is liable to movement and consequent discomfort (although not outright removal) under the relaxation of sleep. It has the additional disadvantage that with the user fully relaxed, such as in the case of sleep, distension in the user's jaw and subsequent opening of the mouth can reduce the sealing effectiveness of the mouthpiece and reduce the efficacy of the CPAP treatment.

The mouthpiece in EP818213 is gripped between the user's teeth; thus a further disadvantage results in that the mouthpiece requires custom orthodontic fitting to ensure that the mouthpiece matches the user's mouth and teeth layout. Custom orthodontic fitting is time consuming and removes the capability of effective mass

manufacture. Consequently, the mouthpiece in EP818213 is expensive, creating a significant barrier to the adoption of the device by the user.

A similar gases delivery mouthpiece, for use with a respirator, is shown in WO90/03199. WO90/03199 discloses an orthodontic device that is adapted to be gripped between the jaws of a user and to accommodate the user's teeth within a series of upper and lower cavities. A base member of the mouthpiece is shaped and fits against the hard palate of the user. This mouthpiece again has the disadvantage of requiring custom orthodontic fitting. Furthermore, as a result of the mouthpiece's substantial thickness and size, the mouthpiece is substantially rigid in the vestibule regions of the mouth. The mouthpiece is clamped in place by an outer shield that engages the outside of the user's lips.

A paper by E Veres entitled "Clinical trial of an oral vestibular shield for the control of snoring" (Journal of the Dental Association of South Africa, January 1993) describes the use of a shield intended to be retained in the vestibule of the mouth to seal the mouth and to promote nasal breathing which has been conventionally considered to be more beneficial than oral breathing. Humidified CPAP treatments delivered orally, however, actually derive greater benefit than those delivered nasally because secondary leakage through the nasal passages during oral delivery is significantly less than oral leakage during nasal delivery. The shield depicted in the paper is formed from flexible ethylene vinyl. The shield is custom trimmed and is custom fitted by heating to a malleable temperature and deformed by applied pressure.

Other possible mouthpiece designs are shown for example by use in self contained underwater breathing apparatus systems, for example as depicted in United States Patent No. 4,862,909. This mouthpiece is a mouth guard type and is clamped between the teeth. A flange extends both in front of and behind the teeth.

Prior art mouthpieces are not well adapted for use in CPAP treatments because they are intended for conscious gripping by the user, and have been found subject to accidental removal with a user in a completely relaxed state such as sleep.

A further prior art mouthpiece that is of relevance is that shown in Figures 1 and 2, this mouthpiece is described in co-pending US patent application number 09/629536. Referring to Figure 1, the mouthpiece is illustrated including an extra-oral

sealing flap 100 and intra-oral sealing flap 101. The extra-oral flap 100 in its natural bias is tapered; the wide-open end of which is shaped to conform to the facial contours around the outside of the mouth of a user. The extra-oral flap 100 is constructed of flexible material, such as silicone rubber. The outer flap 100 is seen in Figure 2 in a bent back position. When the mouthpiece 102 is inserted into the mouth of a user, the outer flap 100 is intended to be in this bent back position to aid insertion. Prior to insertion, the outer flap is bent back by simply pressing on its outer periphery 106, until it snaps into the bent back position, in which it will stay unaided.

The mouthpiece as shown in Figures 1 and 2 also includes a tongue depressor 103 extending from the inner face of the intra-oral sealing flap 101. The tongue depressor 103 further includes a pair of vertically extending spacers 105 which in use may abut against the roof of the wearer's mouth and ensure that the tongue cannot completely block the air passageway. This stops the sleeping user unconsciously blocking the oral passageway and reverting to nasal breathing.

With the prior art mouthpiece of Figures 1 and 2, while the tongue depressor ensures that the tongue does not block the gases outlet, it prevents the user from moving their tongue to moisten the inside of their mouth, causing extreme dryness inside the user's mouth. Furthermore, the tongue depressor can prevent or restrict swallowing. Thus the mouthpiece of this invention has disadvantages that cause users discomfort.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a system for oral delivery of gases, and/or a mouthpiece for oral delivery of gases, which goes some way toward overcoming the above disadvantages or which will at least provide the public with a useful choice.

Accordingly in a first aspect the present invention consists in a mouthpiece comprising:

a vestibular shield having an inner surface and an outer surface, said vestibular shield having a predetermined height which will overlap a user's teeth and gums when positioned in the mouth vestibule of a user;

gases passageway means extending from said outer surface of said vestibular shield to said inner surface of said vestibular shield for allowing the passage of said gases through said mouthpiece;

extra-oral sealing means associated with said gases passageway which is adjustable into one of two conditions, a first condition when said mouthpiece is inserted into a user's mouth being substantially unengaged with a user's face, and a second condition when correctly positioned in a user's mouth being substantially engaged with a user's face and under compression thereupon,

gases diffusing means associated with said gases passageway means and said inner surface that in use causes said gases to be diffused when exiting from said gases passageway.

Preferably said vestibular shield is generally rectangularly-shaped having a central portion which will extend over a user's front teeth and gums when said central portion of said vestibular shield is positioned between the lips and the teeth of the user, and outer portions extending from said central portion which extend along and overlap at least a portion of the user's back teeth and gums when said outer portions of said vestibular shield are positioned between the cheeks and the teeth of the user.

Preferably said gases diffusing means is an outlet part extending through said vestibular shield having at least two gases outlets that allow for a diffused flow of said gases into the patients mouth.

Preferably said at least two gases outlets are angled toward the sides of the user's mouth.

Alternatively said gases diffusing means is a plurality of outlets formed in said vestibular shield, where said gases passageway means is at least partially integrally formed in said vestibular shield.

Preferably said gases passageway means includes gases inlet means for allowing connection of said mouthpiece to a gases supply.

Preferably said gases passageway means includes adjustment means that allows for the distance between said vestibular shield and said extra-oral sealing means to be altered, to allow for adjustment dependant on a user's facial contours.

Preferably said gases passageway means is a tubular passageway and said adjustment means are bellows, corrugations or accordion-like pleats formed in the walls of said tubular passageway that are able to be in use moved from a contracted position to a fully extended position.

Preferably said adjustment means can be extended from said contracted position to a plurality positions before it is in said fully extended position.

Alternatively said adjustment means is a sleeve fittable about said gases passageway means.

Preferably said vestibular shield is formed of a supple material and said gases inlet means is connected to said central portion of said vestibular shield, said gases inlet means comprising a tube formed of a stiffer material than said supple material.

Preferably said inner surface of said vestibular shield includes a plurality of channels extending from said central portion out to the edges of said vestibular shield.

Alternatively said inner surface of vestibular shield includes at least one aperture or ridge that allows for moisture to move about said inner surface of said vestibular shield and the inside of the users mouth.

Preferably said extra-oral sealing means is detachable from said gases passageway means.

Preferably said extra-oral sealing means comprises at least one tapered flap.

Preferably a compressive or frictional force is formed between said vestibular shield and said extra-oral sealing means on the area surrounding a user's lips and is sufficient to secure said mouthpiece is placed on a user and to provide a substantial seal thereto.

Preferably said extra-oral sealing means includes a nose flap connected to at least part of the upper edge of said extra-oral sealing means that in use covers said user's nose.

Preferably said nose flap causes a seal to be formed about said user's nose preventing the user from nasal breathing.

Alternatively a pathway communicates between said nose flap and said mouthpiece to allow for simultaneous or alternative breathing from the user's nose and mouth.

In another aspect the present invention consists in a system capable of being used for oral delivery of gases to a user comprising:

gases supply means,

a gases passageway in fluid communication with said gases supply means, and

a mouthpiece in fluid communication with said gases passageway including an intra-oral sealing means and an extra-oral sealing means and gases diffusing means.

Preferably said extra-oral sealing means is adjustable into one of two conditions, a first condition when said mouthpiece is inserted into a user's mouth being substantially unengaged with a user's face, and a second condition when correctly positioned in a user's mouth being substantially engaged with a user's face and under compression or frictional engagement thereupon.

Preferably said vestibular shield is generally rectangularly-shaped having a central portion which will extend over a user's front teeth and gums when said central portion of said vestibular shield is positioned between the lips and the teeth of the user, and outer portions extending from said central portion which extend along and overlap at least a portion of the user's back teeth and gums when said outer portions of said vestibular shield are positioned between the cheeks and the teeth of the user.

Preferably said gases diffusing means is associated with said gases passageway means and said inner surface and which in use causes said gases to be diffused when exiting from said gases passageway.

Preferably said gases diffusing means is an outlet part extending through said vestibular shield having at least two gases outlets that allow for a diffused flow of said gases into the patients mouth.

Preferably said at least two gases outlets are angled toward the sides of the user's mouth.

Alternatively said gases diffusing means is a plurality of outlets formed in said vestibular shield, where said gases passageway means is at least partially integrally formed in said vestibular shield.

Preferably said extra-oral sealing means includes a nose flap connected to at least part of the upper edge of said extra-oral sealing means that in use covers said user's nose.

Preferably said nose flap causes a seal to be formed about said user's nose preventing the user from nasal breathing.

Alternatively a pathway communicates between said nose flap and said mouthpiece to allow for simultaneous or alternative breathing from the user's nose and mouth.

In yet another aspect the present invention consists in a system capable of being used for oral delivery of gases to a user comprising:

a mouthpiece,

a breathing tube, and

decoupling means for connecting said mouthpiece to said breathing tube, said decoupling means comprising a connection tube including means to diffuse gases.

Preferably said connection tube is an L-shaped elbow including a swivel joint and the end of said elbow that connects with said tube tapers from said joint to said end.

Preferably said tapered end includes said means to diffuse gases, wherein said means to diffuse gases are a plurality of tapered slots.

Alternatively said connection tube is an L-shaped elbow including a swivel joint, wherein said means to diffuse said gases includes a circular ledge formed in said elbows circumference of smaller diameter than said elbows diameter and a plurality of apertures in said ledge that allow for gases to be diffused from said elbow.

Preferably said connection tube is formed in a hard plastics material.

Alternatively said connection tube is formed is a soft plastics material.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

One preferred form of the present invention will now be described with reference to the accompanying drawings.

Figure 1 is a perspective view of a prior art mouthpiece having an outer flap in an "in use" position.

Figure 2 is a perspective view of the prior art mouthpiece of Figure 1 where the outer flap is bent back in a "locating" position.

Figure 3 is a side elevational view of the system according to the present invention as being used by a user.

Figure 4 is an exploded perspective view of a first form of the mouthpiece of the present invention including gases diffusing outlet.

Figure 5 is a perspective view of the vestibular shield of the first form of the gases diffusing mouthpiece of the present invention.

Figure 6 is a plan view of vestibular shield of the first form of the gases diffusing mouthpiece of the present invention.

Figure 7 is a perspective view of a vestibular shield having channels or apertures to allow for moisture flow about the shield.

Figure 8 is a front view of an outer flap having an integral nose flap, which may be used with any of the embodiments of the mouthpiece of the present invention.

Figure 9 is a side view of the outer flap having an integral nose flap of Figure 8.

Figure 10 is a perspective view of the outer flap having an integral nose flap of Figure 8.

Figure 11 is an exploded perspective view of a second form of the mouthpiece of the present invention having an alternative gases diffusing outlet.

Figure 12 is a side cross sectional view of vestibular shield of the first form of the gases diffusing mouthpiece of the present invention.

Figure 13 is a side view of the vestibular shield of the second form of the gases diffusing mouthpiece of Figure 11.

Figure 14 is a side view of an elbow piece and associated tubing, connectable and to be used with any one of the embodiments of the mouthpiece of the present invention.

Figure 15 is a perspective view of a further form of an elbow piece, connectable and to be used with any one of the embodiments of the mouthpiece of the present invention.

Figure 16 is a cutaway view of the mouthpiece with split flow diffusing with an outer flap in use.

Figure 17 is a block diagram of a respiratory system according to the preferred embodiment of the present invention.

Figure 18 is a cross-sectional plan view of a mouthpiece of the present invention including extendable means between the vestibular shield and extra-oral sealing means, where the extendable means is in a contracted position.

Figure 19 is a cross-sectional plan view of a mouthpiece of the present invention including extendable means between the vestibular shield and extra-oral sealing means, where the extendable means is in an expanded position.

Figure 20 is an exploded perspective view of an alternative form of the mouthpiece of the present invention including alternative extendable means between the vestibular shield and extra-oral sealing means.

Figure 21 an exploded perspective view of the alternative form of the mouthpiece of the present invention showing the gases passageway and sleeve that form the extendable means.

Figure 22 a perspective view of the alternative form of the mouthpiece of the present invention showing the gases passageway and sleeve in association.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

While the invention may be susceptible to embodiment in different forms, there is shown in the drawings, and herein will be described in detail, specific embodiments with the understanding that the present disclosure is to be considered an exemplification of the principles of the invention, and is not intended to limit the invention to that as illustrated and described herein.

The present invention provides a novel system for oral delivery of gases pressurised above ambient to a user and is especially suited for use in the oral delivery of air in continuous positive airway pressure (CPAP) treatments of sleeping disorders such as sleep apnoea. As shown in Figure 3, the system includes a mouthpiece 1 which is connected by a connection 2 to a breathing circuit 3.

Gases Diffusing Shield

One preferred embodiment of the present invention is illustrated in Figures 4 to 6. In this embodiment, the mouthpiece 1 includes a vestibular shield 21 being a generally flat and generally rectangularly-shaped member in front elevation having a curved profile that reflects the curvature of a user's jaw and in turn the curvature of the labial vestibule region. A gases passageway extends through the vestibular shield from an inlet 22 to an outlet part 20 having two diffusing outlets 23, 24. The mouthpiece 1 also has an outer flap 25 similar to that described in relation to Figures 1 and 2 and that described in US co-pending patent application 09/629536.

The outer flap 25 is tapered and the wide open end is shaped to conform to the facial contours around the outside of the mask of a user. The narrow end terminates in an inlet 26 of substantially circular cross section and which is attached on one side to a breathing or inspiratory tube and the other to a connector 27 that connects the outer flap 25 to the vestibular shield 21. The connector 27 is made from a substantially rigid plastics material and broadens in cross-section from a circular end 34 to an elongated oval end 35 that is attached to the inlet 36 of the outlet part 20. In other forms of the present invention the connector may be formed in a soft plastics material such as silicon, so that it provides additional flexibility to the mouthpiece to enable the mouthpiece to better conform to the user's face.

The outer flap 25 and vestibular shield 21 are preferably formed in a soft and supple material such as silicon. The connector 27 between the outer flap 25 and vestibular shield 21, and outlet part 20 are made of a stiffer material, such as a hard plastics material, for example, polycarbonate. In the form shown in Figure 4, attached to the outlet side of the vestibular shield 22 are overmoulding outlets 32, 33 that are made from a supple material and that fit over the outlets 23, 24 of the outlet part 20. When assembled, as the vestibular shield 21 is made from a supple material, the outlet

part 20 is able to be pushed through the inlet 22 in the vestibular shield 21 and the outlets 23, 24 fit into the overmoulding outlets 32, 33.

The outlet part 20 is a substantially tubular U-shaped piece, where the top (or inlet 36) of the U is open and connected to the elongated end 33 of the connector 27. The arms of the U form gases passageways that are oval in cross-section that lead to the outlets 23, 24 that pass gases from the mouthpiece 1 into the user's mouth. In this manner the gases flowing through the mouthpiece 1 flow through the inlet to the outer flap 37, through the connector 27, and are diverted through each of the outlets 23, 24 and around the sides of the user's mouth. Hence the gases flowing into the user's mouth are effectively diffused.

The purpose of splitting or diffusing the gases flow in this manner is to prevent the user's tongue from covering the outlet and disrupting or stopping the gases flow and thus treatment provided to the user. If the prior art mouthpiece shown in Figures 1 and 2 had no tongue depressor to keep the user's tongue at the bottom of the user's mouth the user could inadvertently during sleep allow their tongue to cover the gases outlet. With a diffused outlet such as that shown in Figure 4 where at least two outlets direct flows substantially to the sides of the users mouth as opposed to the centre of the mouth it is not possible for a user to place their tongue inadvertently over both or even one of the outlets 23, 24. Furthermore with the absence of a tongue depressor and the diffusion of gases flow the user is still able to lift their tongue between the two arms of the outlet part and moisten their mouth, preventing dryness of the mouth. Also by allowing movement of the users tongue the mouthpiece of the present invention the user can swallow without difficulty. As a consequence of these advantages the mouthpiece in this form proves to be more comfortable to a user.

It is preferred that the outlet part 20 is made from a hard plastics material, but it could be made of a softer plastics material such as silicon.

Formed above the outlet part 20, preferably in the vestibular shield 21, is an abutment 28 and an area 29 in which the user may place his or her teeth. The abutment 28 prevents inadvertent movement of the users' teeth away from or off the area 29. The abutment 29 also assists in the maintaining of the vestibular shield 21

between the users' lips and teeth retaining the mouthpiece in and about the users' mouth.

A notch 30 is provided centrally in the upper edge of the vestibular shield 21 to accommodate the upper frenal attachment. A slight bead 30 may be provided around the edge of the vestibular shield 21 for user comfort, with the vestibular shield 21 otherwise being very thin for additional suppleness.

Vestibular Shield with Apertures

In an alternative embodiment of the vestibular shield that may be used with the mouthpiece of the present invention is shown in Figure 7. The vestibular shield 40 has a plurality of ventilation apertures 41, 42 extending out from the centre of the shield 40. The apertures are effectively channels spaced over the diameter of the shield 40 and are provided to allow moisture to move about the shield 40 to prevent dryness of the inside of the user's mouth.

As already discussed the vestibular shield 40 is preferably made of a soft and supple material, such as silicon. The shield 40 is preferably thin and has channels such as that shown in Figure 7, although other forms of apertures or channels may be possible such as the shield being formed from a porous material or holes or slots being formed in the shield. It is preferred that the shield has a textured finish at least on its inside. The channels and the textured finish therefore allow for moisture to move around the vestibular shield and move from inside the shield to prevent dryness on the inside of the patient's mouth and to prevent the shield sticking to the inside of the patient's cheeks.

Another form of a vestibular shield having a diffusing outlet that may be used with the mouthpiece of the present invention is shown in Figures 11 to 13. This vestibular shield 50 is preferably used with the outer flap 25 as described above. The shield 50 has a notch 51 for the upper frenal attachment and may have a bead 52 provided around the edge of the shield 50, similar to that of Figures 4 and 7. A diffused outlet 54 is formed in the vestibular shield 50 such that gases received from the inlet 53 move into an elongated recess 58 formed in the central area of the shield 50. There are a number of outlets 55, 56 formed in the inner wall 57 of the shield 50. Extending from the outer wall of the shield 50 is a preferably tubular shield inlet (now

shown) that is connected to the outer flap 25 inlet 37, preferably by threaded connection, but other means of attachment may be used. In use, gases flow from the inlet 37 of the outer flap 25 through the shield inlet 58, into the elongated recess formed in the central area of the shield 50 and out of the diffusing outlets 55, 56 into the user's mouth.

Adjustable Mouthpiece

A further form of the mouthpiece of the present invention is shown in Figures 18 and 19. Here the mouthpiece 300 includes adjustment means 301 located between the vestibular shield 302 and outer flap 303 that allows for the distance to be altered between the shield 302 and flap 303, to allow for adjustment dependant on a user's facial contours. The adjustment means 301 is formed in the tubular gases passageway 301 between the vestibular shield 302 and outer flap 303. The adjustment means are bellows, corrugations or accordion like pleats 305 formed in the walls of said tubular passageway 304. The pleats 305 allow for the vestibular shield 302 and outer flap 303 to be moved apart or pushed together to accommodate varying user's mouths and facial contours. In use, the pleats 305 may be extended from a contracted position (as shown in Figure 18) to a fully extended position (as shown in Figure 19) and vice versa. Furthermore, the user may extend or contract the pleats 305 to any position in between the fully extended or contracted position and the mouthpiece 300 will stay in that position due to the stiffness of the material that the pleats are formed in. In the preferred form of this mouthpiece the tubular passage and pleats are formed in a stiff plastics material.

Referring now to Figure 16, use of the mouthpiece according to Figures 4 to 6 is depicted. With the present mouthpiece 1, the vestibular shield 21 sits inside the user's lips 90, 91 and the outer flap 25 sits about the outside of the user's lips. Thus a seal is formed by the pressure caused by the outer flap on the outside of the users' lips and the opposing forces of the vestibular shield on the inside of the users' lips. Once the mouthpiece 1 is correctly positioned in the mouth 93, the outer flap 25 may be adjusted into its operational position by pressing on its outer periphery until it snaps back and depresses against the outside of the mouth. Due to the relative position of the vestibular shield 21 and the outer flap 25, the outer flap is unable to fully reach its

natural bias and thereby inflicts the compressive force on the outside of the users' mouth.

As is illustrated in Figure 16 the abutment 28 prevents the user's top row of teeth 94 from slipping from the mouthpiece and therefore assists in preventing accidental removal of the mouthpiece. Although not shown in Figure 16, an additional abutment on the lower side of the mouthpiece may be provided to stop the lower row of teeth from slipping from the mouthpiece.

An alternative form of the mouthpiece of the present invention is shown in Figures 20 to 22. Here the mouthpiece 400 includes an alternative adjustment means 401, to that shown in Figures 18 and 19. This form of the adjustment means 401 is the association of a sliding sleeve 402 with the tubular gases passageway 403. In this form the adjustment means 401 is located between the vestibular shield 404 and outer flap 405, and allows for the distance to be altered between the shield 404 and flap 405.

The sleeve 402 is attached to the flap 405 by way of an interference fit. Although not shown in the figures the flap 405 may during its moulding be over-moulded about the sleeve 402.

The gases passageway 403 shown in Figures 20 to 22 has at one end a circular opening 406 and the other end two oval exit ports 407, 408 that deflect gases passing through the mouthpiece to the sides of a patient's mouth, similar to those ports described in relation to Figures 4 to 6. The vestibular shield 404 is associated with the tubular passageway 403 by fitting the tubular gases passageway 403 through the aperture 414 in the shield 404. Due to the flexible nature of the material the shield 404 is made from, the shield 404 fits snugly about the tubular passageway 403, which does not allow for gases to leak through the aperture 414.

The gases passageway 403 has a series of elongate indentations 413 provided on its outer surface at its circular opening end 406. Although not shown, a set of diametrically opposed indentations similar to those indicated as 413 are provided on the passageway 403. The passageway 403 also has two diametrically opposed elongate protrusions (of which only one protrusion 422 is shown in Figures 20 and 21) located on its outer surface nearer the circular opening end 406. These elongate protrusions 422 are offset from the indentations 413 and are preferably spaced around

the circumference of the gases passageway such that a 90 degree angle would be formed between each set of indentations and each elongate protrusion.

The gases passageway 403 also has at least one stop projection 423 located on its body. Preferably the stop projection 423 is integrally on the gases passageway 403 when it is moulded. The projection 423 abuts against the upper edge of the sleeve 402 and prevents the sleeve 402 from travelling too far along the gases passageway 403.

The sleeve 402 is preferably tubular in shape and made from a plastic material. The tubular shape of the sleeve 402 allows for the sleeve to be deformed, even though non-malleable plastics materials such as polycarbonate are used. To assist with the deformation of the sleeve 402 cantilever extensions 411, 412 are provided on the sleeve 402. These ensure that the sleeve can be deformed without the sleeve 402 cracking or breaking.

The sleeve 402 has an inner skirt 415 and an outer portion 424. The outer portion 415 is a circular tubular section that is integrally formed with the skirt 415. The skirt 415 has two protrusions 409, 410 that extend from the inner surface of the skirt 415 toward the central axis through the sleeve. In particular, during forming of the sleeve 402, the skirt 415 and outer portion 424 are fused together at the protrusions 409, 410. The protrusions 409, 410 are formed on one outer edge of the skirt 415 and link to the outer portion 424. The cantilever extensions 411, 412 are integrally formed on the other edge of the skirt 415 during moulding and key hole apertures 427, 428 are formed in the skirt 415 that extend partially into the cantilever extensions 411, 412. The purpose of the key hole apertures 427, 428 are to prevent the sleeve 402 from disengaging from the gases passageway 403 after being assembled. Once the sleeve 402 is assembled about the gases passageway 403 the nodules 425, 426 are located within the key hole apertures 427, 428 and are able to slide within the apertures 427, 428, but prevent the sleeve 402 being removed from the gases passageway 403 as they abut against the ends of the apertures 427, 428. Although not apparent in Figures 20 to 22, complimentary key hole apertures and nodules are provided on the diametrically opposed sides of the gases passageway 403 and sleeve 402.

Each of the protrusions 409, 410 and extensions 411, 412 are formed on diametrically opposed sides of the sleeve 402. Elongated apertures 416, 417 are

formed on the inner surface of the skirt 415. The apertures 416, 417 are diametrically opposed and are formed in the skirt 415 at a position on the circular skirt that is 90 degrees from the diametrically opposed protrusions 409, 410.

The outer portion 415 of the sleeve 402 has regions 418, 419 that are diametrically opposed and are thicker in width than the rest of the outer portion. These regions 418, 419 are effectively finger pads that may be provided with small protrusions 420, 421 or the like that allow for traction between a user's fingers and the regions 418, 419.

The regions 418, 419 are offset from the protrusions 409, 410 such that if sidewise forces A and B (shown in Figure 22) are placed on the finger pad regions 418, 419 the sleeve is deformed from a circular shape to a more elongated oval shape. As the regions 418, 419 and protrusions 409, 410 are offset from one another when the regions are depressed or squeezed together the protrusions 409, 410 on the sleeve 402 are pushed upwards and away from each other.

When assembled, the mouthpiece of the alternative form as shown in Figures 20 to 22, the sleeve 402 fits about the tubular passageway 403. The sleeve is prevented from moving to the exit port end of the passageway 403 by the edge of the sleeve 402 abutting the projections 423. The fitting of the elongate protrusions 422 into the elongated apertures 416, 417 formed in the inner skirt 415 of the sleeve 402 prevent rotation of the sleeve 402 and outer flap 405 relative to the gases passageway 402.

In use, a user may adjust the mouthpiece 400 by squeezing the regions 418, 419 wherein the protrusions 409, 410 extending from the inner surface of the skirt 415 are released from one of the indentations 413. The user may then slide the sleeve 402 and outer flap 405 along the gases passageway 402 and release the regions 418, 419 whereby the protrusions 409, 410 will be released back into an alternative one of the indentations 413. Therefore, the distance between the shield 404 and outer flap 405 can be reduced or increased depending on the user's requirements in this manner. In the preferred form there are three indentations 413, as shown in Figure 20, where each of these relates to one of three positions that a patient can adjust the distance between

the shield 404 and outer flap 405. In other forms of the mouthpiece 400 the gases passageway may be provided with any number of indentations.

Elbow Connector

Attention is now directed to Figure 3. It has been found that an additional factor in the effectiveness of any mouthpiece, including mouthpiece 1, is the manner in which the mouthpiece is connected to the breathing circuit 3. The weight of the breathing circuit 3, and any attempted movement of one other of the breathing circuit 3 and the mouthpiece 1 relative to the other, is one of the largest influences tending to dislodge a mouthpiece 1 from the mouth of a user. It must be noted that the mouthpiece 1 must remain in position and maintain a seal during all sleep when the user has no muscle tone.

The connection 2 as provided in the present invention between the breathing circuit 3 and the mouthpiece 1 decouples the mouthpiece 1 from the breathing circuit 3. As a result, the connection 2 is effective in reducing the forces placed on the mouthpiece 1 by the breathing circuit 3 when the user moves around during sleep. In the preferred sleeping position, the breathing circuit 3 is laid across the chest 4 of the user, and may be secured to the user's bed clothes or sleeping garments. The breathing circuit 3 is preferably laid on the chest of the user to take the weight of the breathing circuit 3 off of the mouthpiece 1.

To connect between the gases outlet 5 which is vertical when the user is lying on his or her back and the breathing circuit 3 which is generally horizontal, an L-shaped elbow 6 is incorporated in the connection 2. The elbow 6 is formed at a right angle and provides a positive pressure on the mouthpiece 1 to maintain the mouthpiece 1 in the user's mouth. The elbow 6 may include a swivel joint and may be disconnected from gases outlet 5. The connection 2 further includes an extremely flexible connecting tube 7 provided between the elbow 6 and the breathing circuit 3. The connecting tube 7 is preferably connected to the breathing circuit 3 by a swivel joint 8. The elbow swivel joint 6 allows for movement of the connection tube 7 relative to the mouthpiece 1. The swivel joint 8 allows for movement of the connection tube 7 relative to the breathing circuit 3. It is to be understood that one or

both of the swivel joints 6, 8 could be eliminated, but the preferred embodiment includes swivel joint 8.

Referring to Figure 14 an alternative form of the elbow described above is shown. In this form the elbow piece 70 is shown as attached to a connecting tube 71. The elbow piece 70 has an outlet 72 attached to the inlet of a mouthpiece (37 on Figure 4) such that gases flow through the connection tube 71 through the elbow piece 70 and out the outlet into the mouthpiece and subsequently into the user's mouth. The elbow piece is substantially L-shaped and preferably includes a swivel joint 73. Additionally a swivel joint may be provided on the connecting tube side of the other connector, namely swivel joints 74. The end 75 distal to the outlet is substantially tubular in shape and tapers from a wider diameter at the joint 74 and narrows towards the connecting tube 71 disposed along the length of a diffusing part 75 are elongate apertures that are also preferably tapered and shaped rather at the joint 74 end and narrowing toward the connecting tube 71. A plurality of these apertures 76 are disposed about the diffusing part and allow for gases exhaled by the user through the mouthpiece and outer connector to diffuse into the ambient air. The tapered apertures also have the additional advantage of diffusing the gases in a direction along the connection tube 71 and therefore away from the user. Also these gases flow away from anyone who may be facing the user, such as the user's partner, for example, during sleeping. Additionally the diffuser 75 also allows for low noise diffusion of exhaled gases.

Referring now to Figure 15, which shows a further alternative form of an elbow that may be used with a mouthpiece of the present invention. The elbow 80 again is substantially L-shaped and connects at an outlet end to the inlet of a mouthpiece. The inlet 82 is connected to a connecting piece of tube such as that shown in Figure 3 or the connecting tube 71 of Figure 14). In this embodiment the elbow connector 80 has diffusing means formed on a ledge 83 formed by the reduction in the diameter from the body 84 of the elbow 80 and the inlet piece 82. In use gases flow in through the inlet 82 in the direction of arrow A and exhaled gases are diffused out the plurality of apertures formed about the circular ledge 83 (although only one aperture 85 is labelled it is preferred that a number of apertures are formed about the circular ledge. Due to

the high pressure of the incoming gases the lower pressure outgoing gases cause less effect as they are pushed to the edges and out the apertures 85 on the incoming disk. Again, like the embodiment of the other as shown in Figure 4 the exhaled gases are directed away from the user and the user's partner and the noise of gases diffusing is reduced.

Nose Flap

Reference is now made to Figures 8 to 10 in which a further embodiment of the outer flap that may be used with the mouthpiece of the present invention is illustrated. The outer flap 25 is provided with a nose flap 61. In use, when the mouthpiece is inserted within the patient's mouth and the outer flap 25 is compressed about the patient's mouth (such as that shown in Figure 16) the nose flap 61 sits over and potentially about the patient's nose. The nose flap 61 may seal about the patient's nose and to prevent the patient from breathing through their nose and reducing the effect of ventilation or the like treatment provided through the mouthpiece. In alternative forms of the mouthpiece with nose flap a pathway or area of communication may exist between the flap 61 and mouthpiece, allowing for the passing of gases, such that a full face mask that allows either oral or nasal breathing is provided.

It will be appreciated that as well as providing a substantially airtight seal the addition of the outer flap provides enough compressive force on the mouth to keep the mouthpiece and conduit in place without the need for straps. This allows the administering of CPAP therapy to be considerably less obtrusive than traditional methods.

A typical respiratory humidification circuit such as might employ the present invention is shown diagrammatically in Figure 17, and includes the respirator 200, humidifier 201, and the associated respiratory breathing tubes 202 and 203. A user 204 under treatment is shown, with the mouthpiece of any of the abovementioned embodiments 205, located in the mouth of the user 204.

Advantages

From the above it can be seen that the present invention provides a system including mouthpiece for oral delivery of CPAP treatment which at once is low cost

and effective. Unlike other appliances the mouthpiece used in the present invention does not require custom orthodontic fitting as the mouthpiece does not rely on accurate alignment with the user's teeth or the user's palate to provide location and retention within the user's mouth, but instead resides in the vestibule between the teeth and lips and the teeth and cheeks, and the lateral and vertical extension of a vestibular shield requires that the user's lips be actively manipulated for the vestibular shield to be removed. Furthermore the vestibular shield is provided with an outlet that allows for diffusion of the gases provided to the user and thus the mouthpiece does not require any tongue depressor. The mouthpiece and vestibular shield thus prevent a user blocking the flow of gases from the mouthpiece, yet is more comfortable for the user than prior art devices. With the addition of the extra-oral flap the mouthpiece and associated tubing is held securely in place without the need for external strapping, and an effective seal is created around the user's mouth.

DATED THIS 26th DAY OF March 2003
AJ PARK
PER N Chelley
AGENTS FOR THE APPLICANT

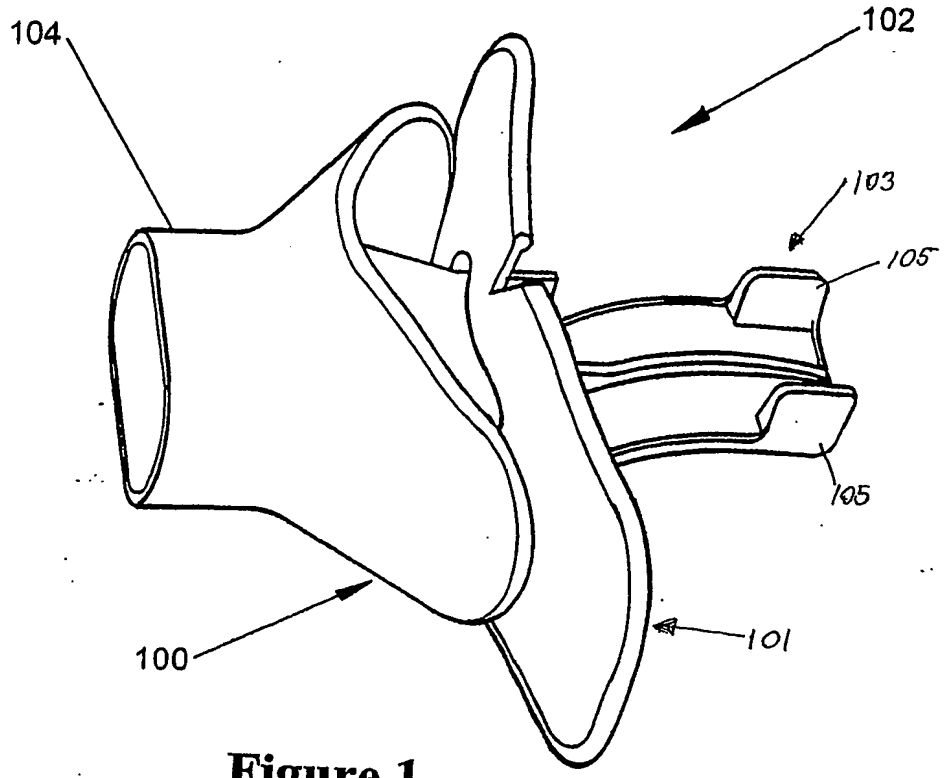


Figure 1

PRIOR ART

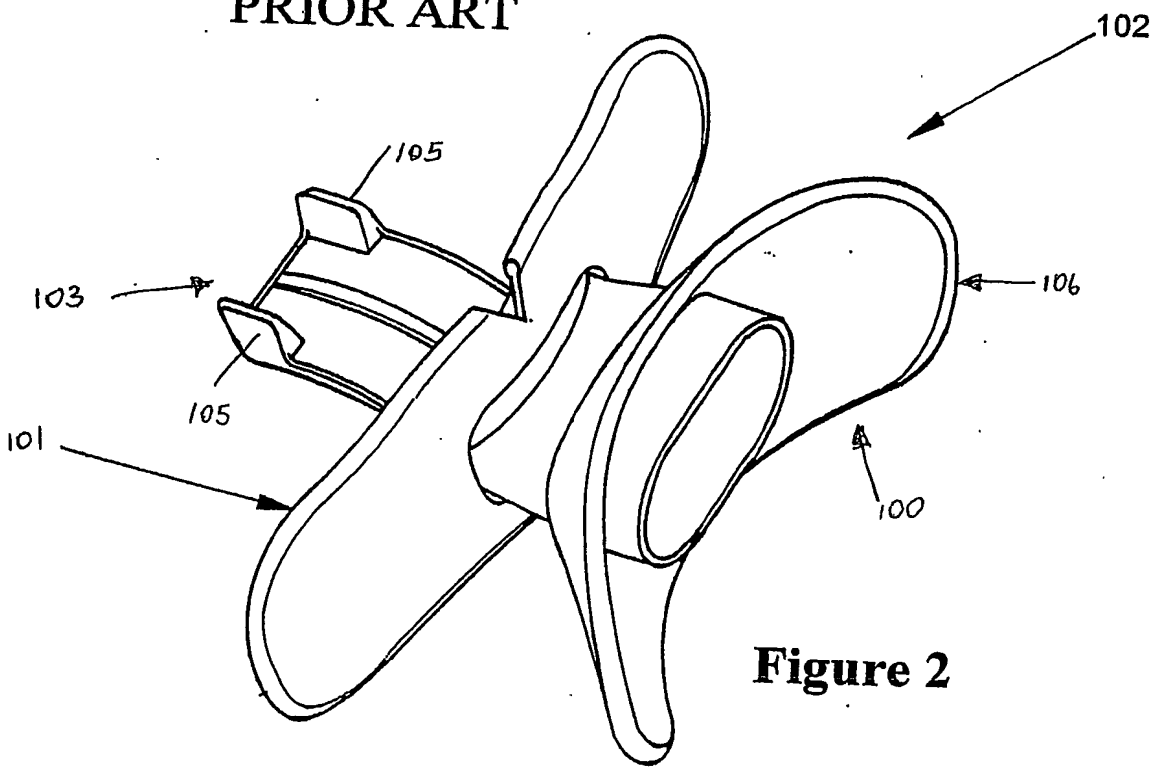


Figure 2

PRIOR ART

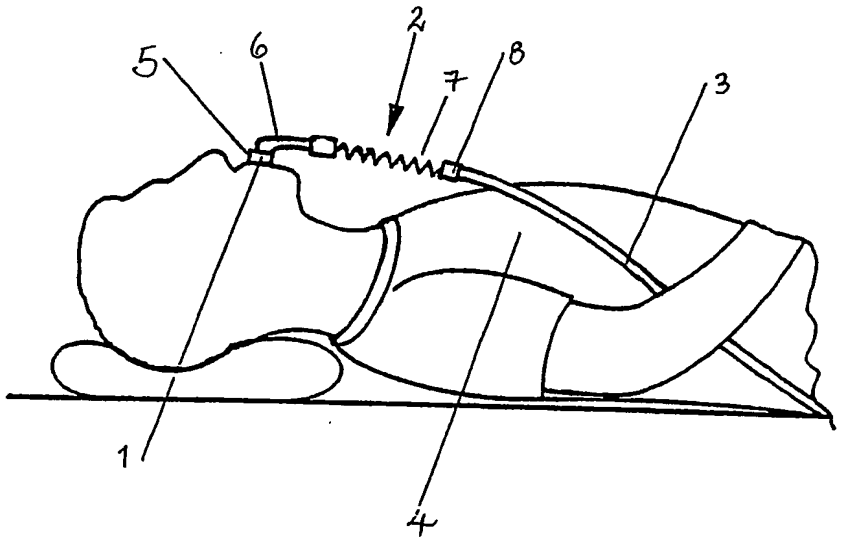


Figure 3

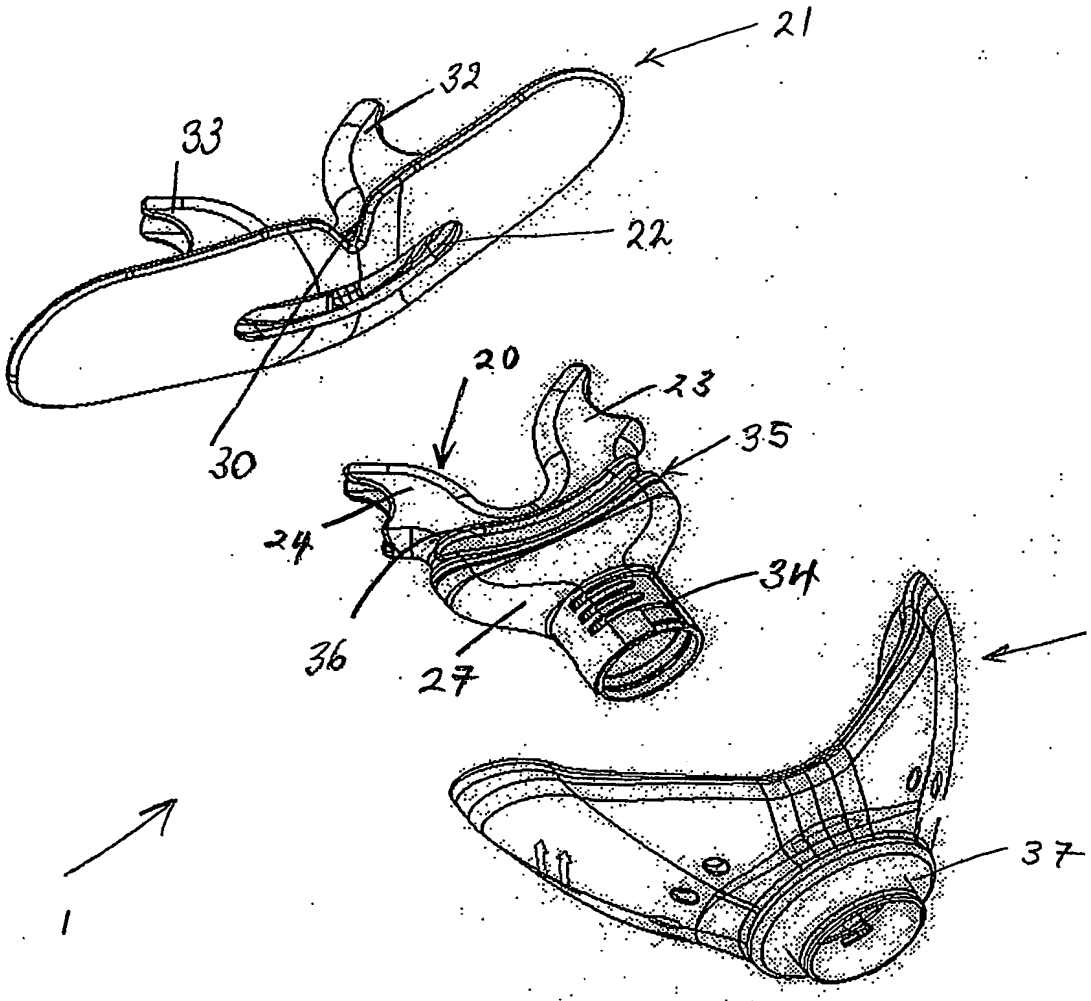


Figure 4

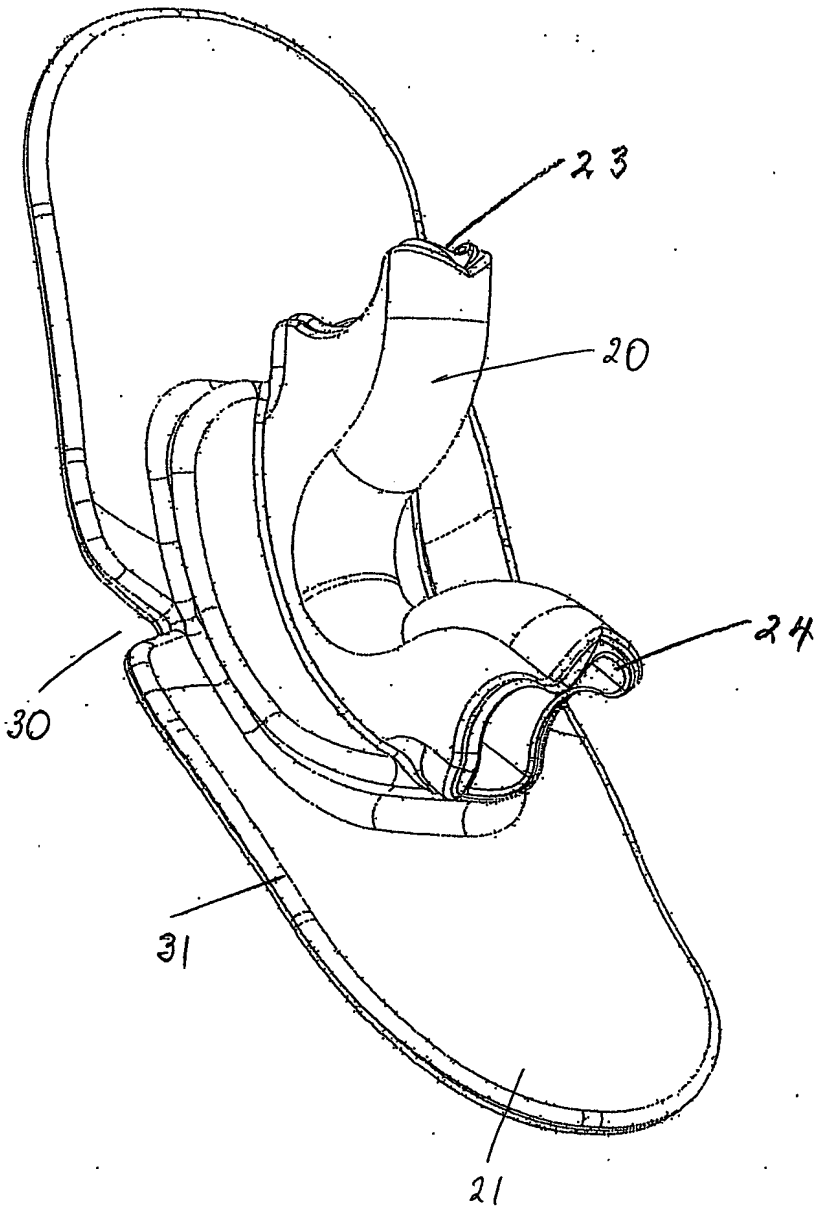


Figure 5

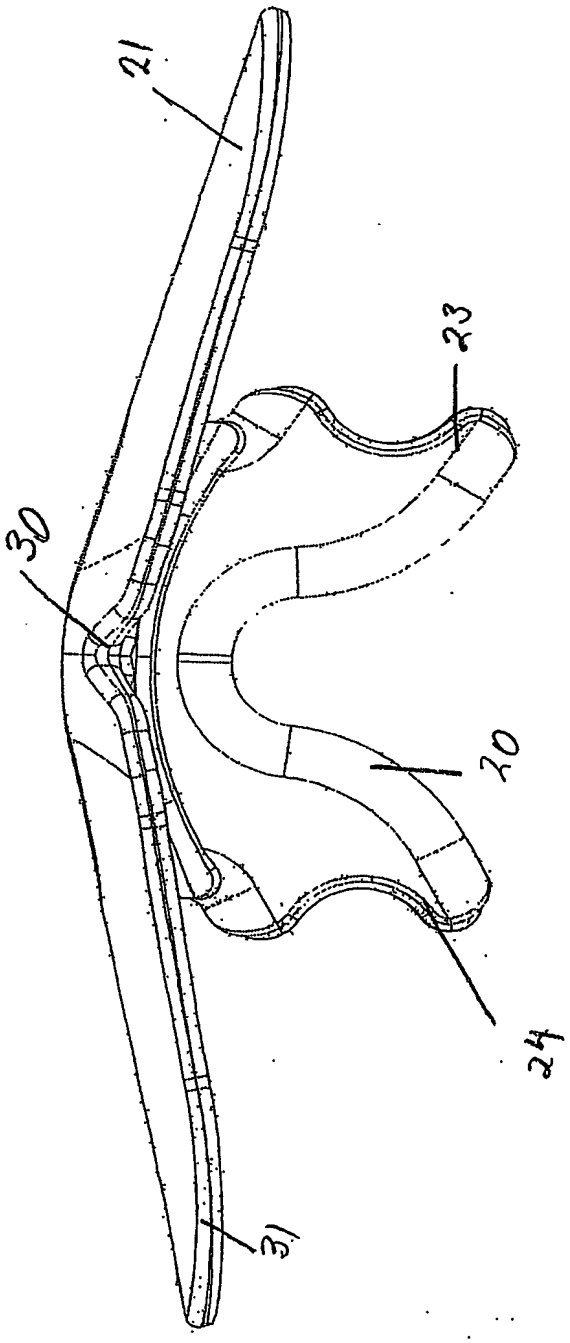
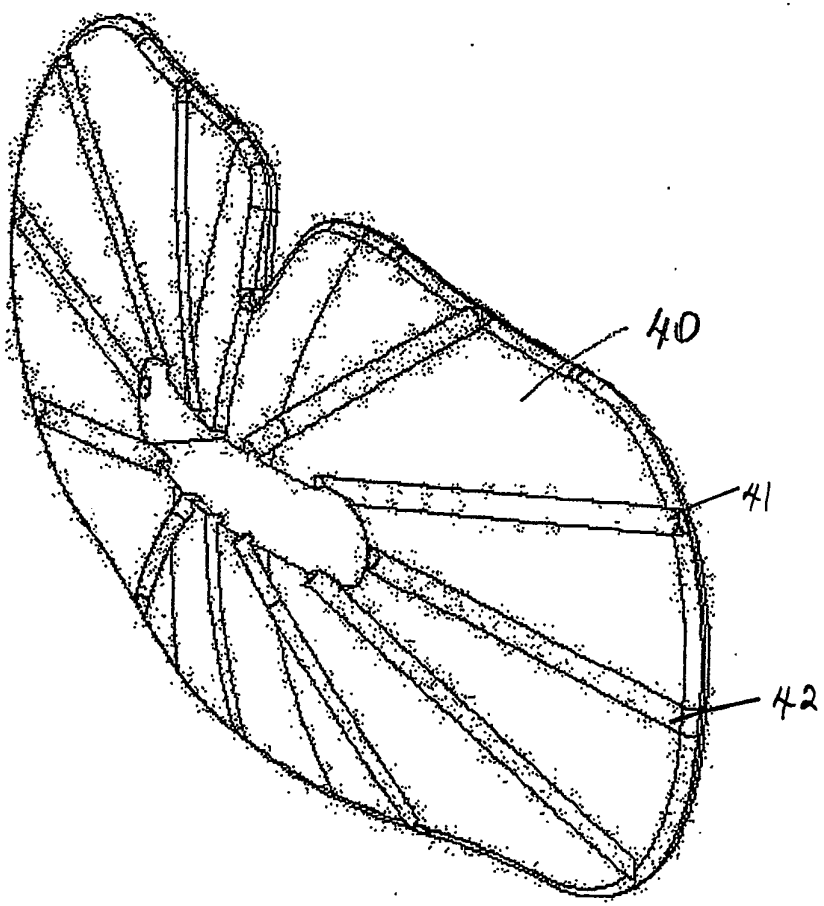


Figure 6



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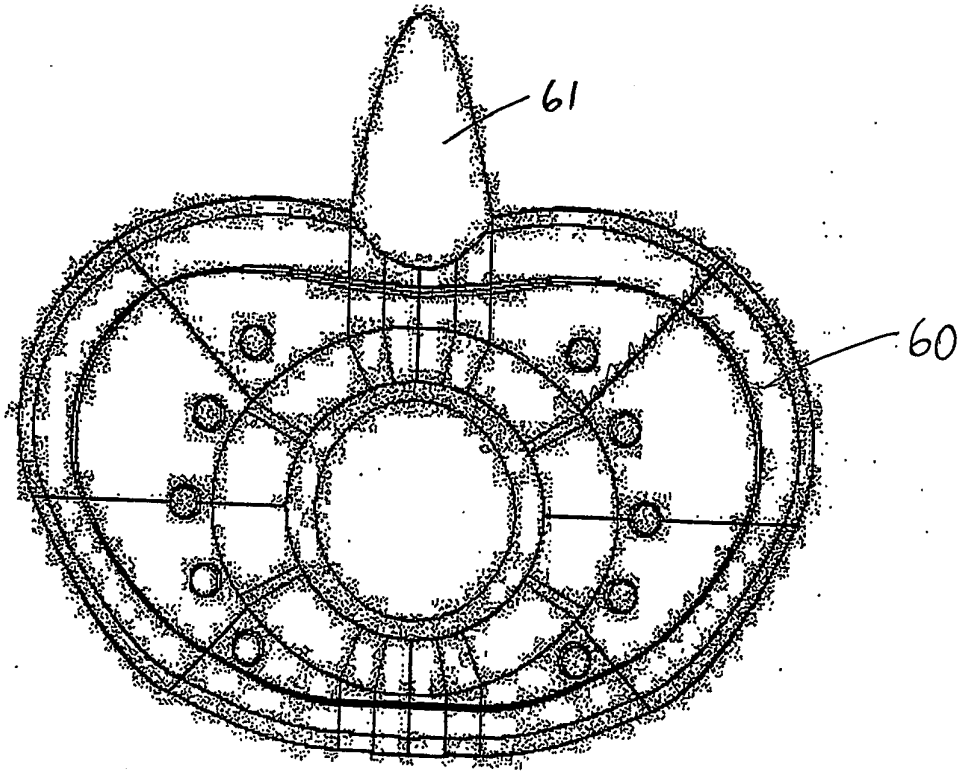


Figure 8

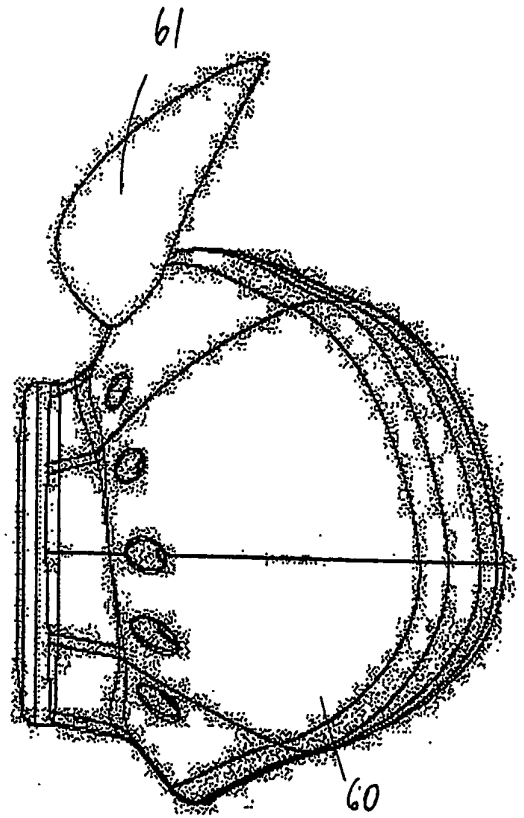


Figure 9

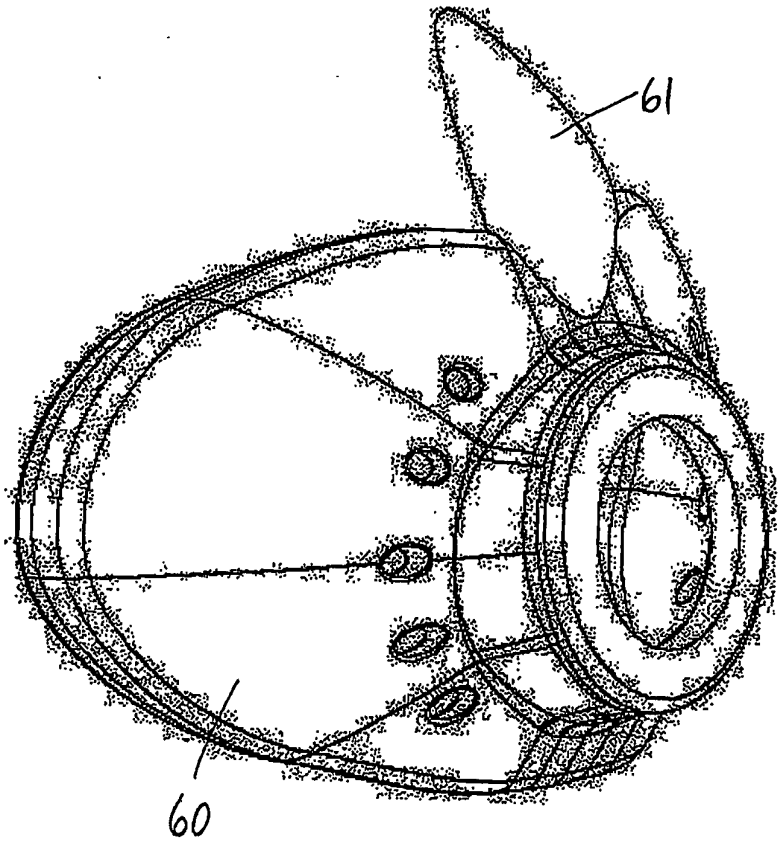


Figure 10

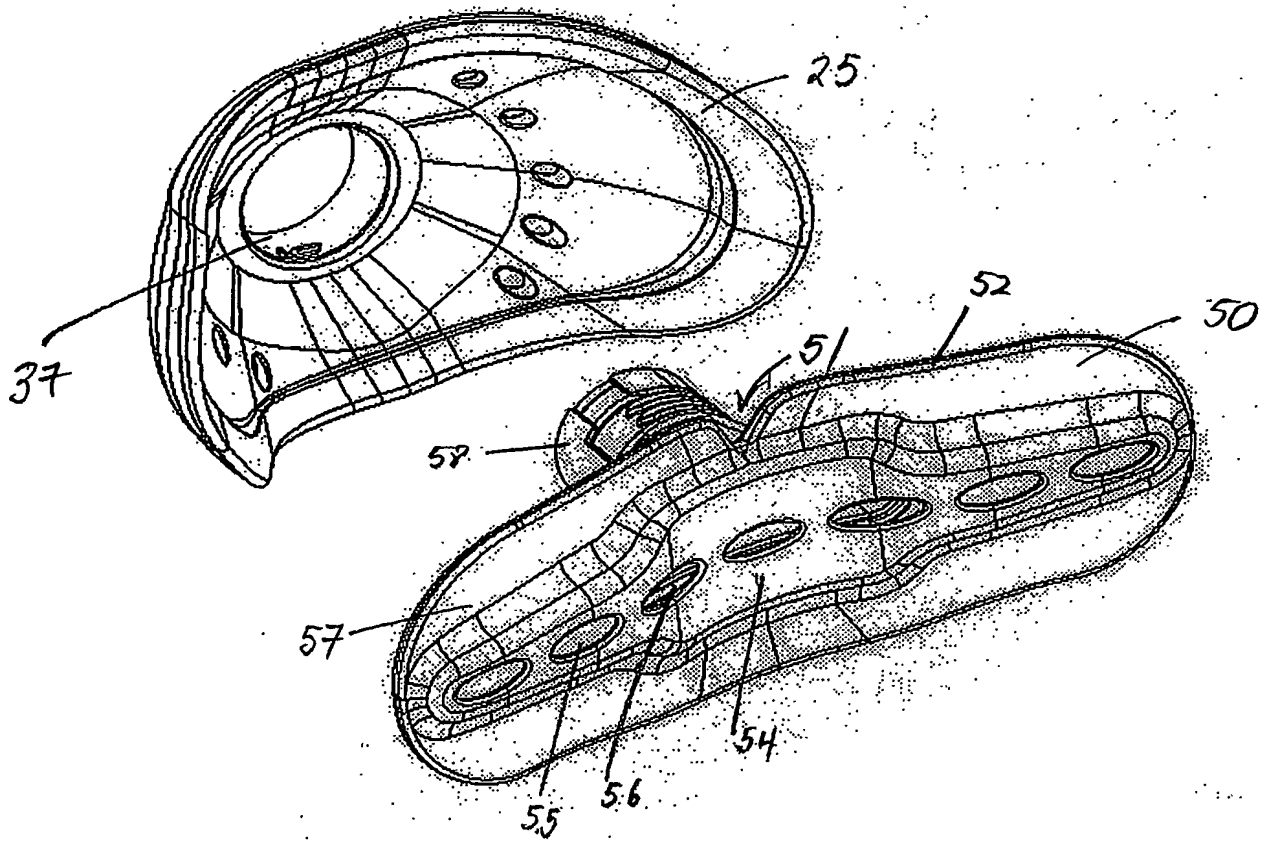
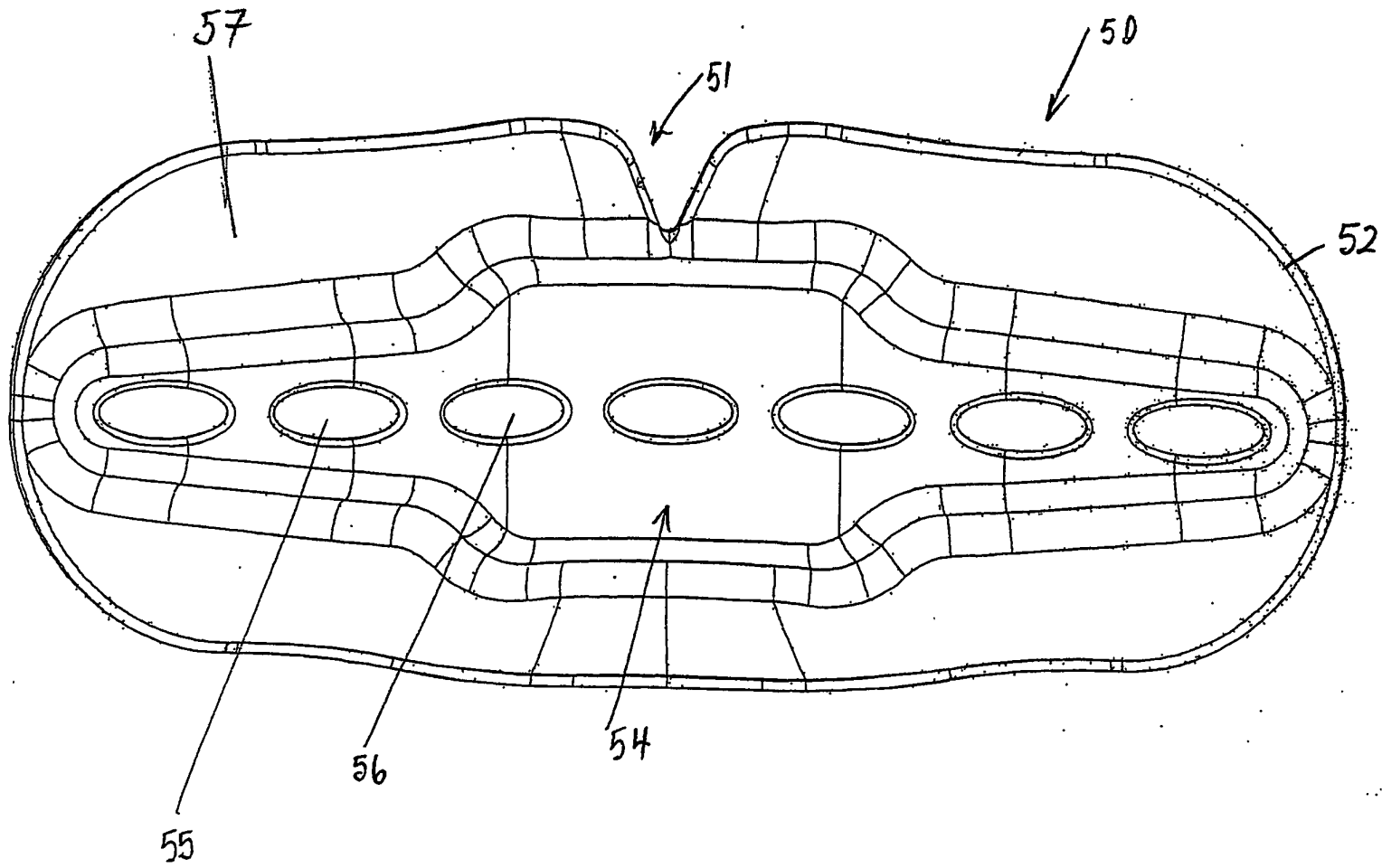


Figure 11



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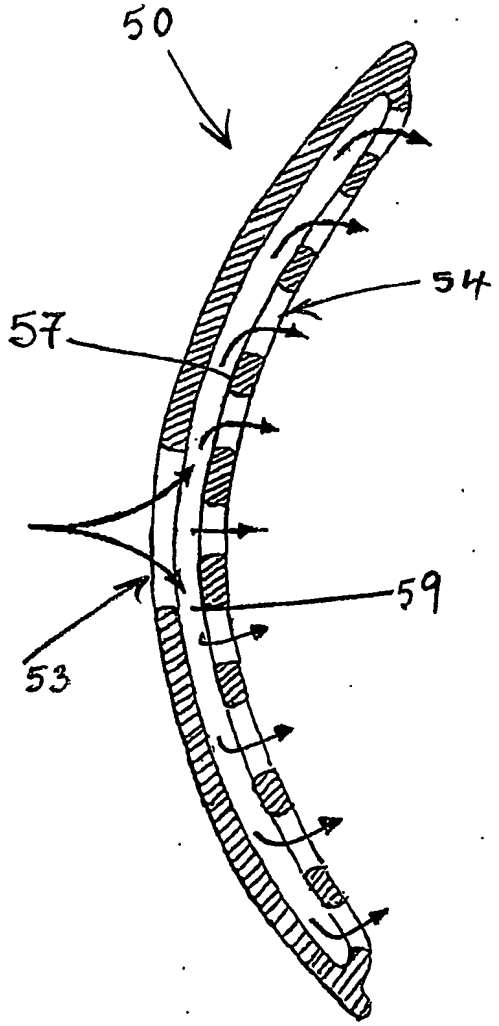

Figure 13

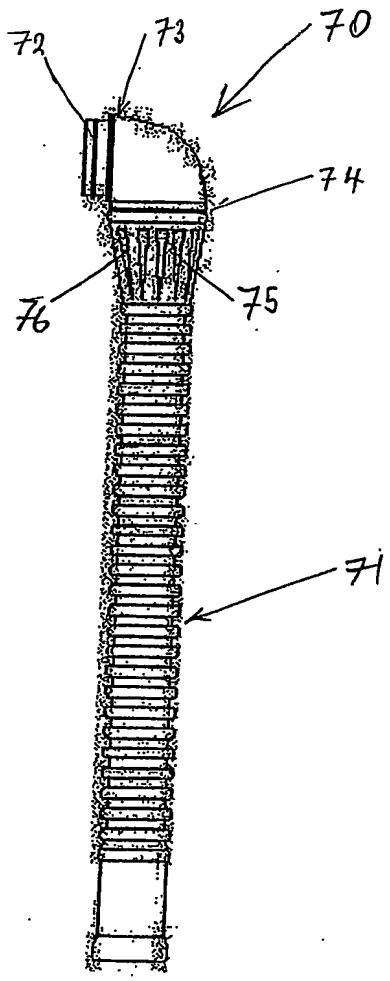

Figure 14

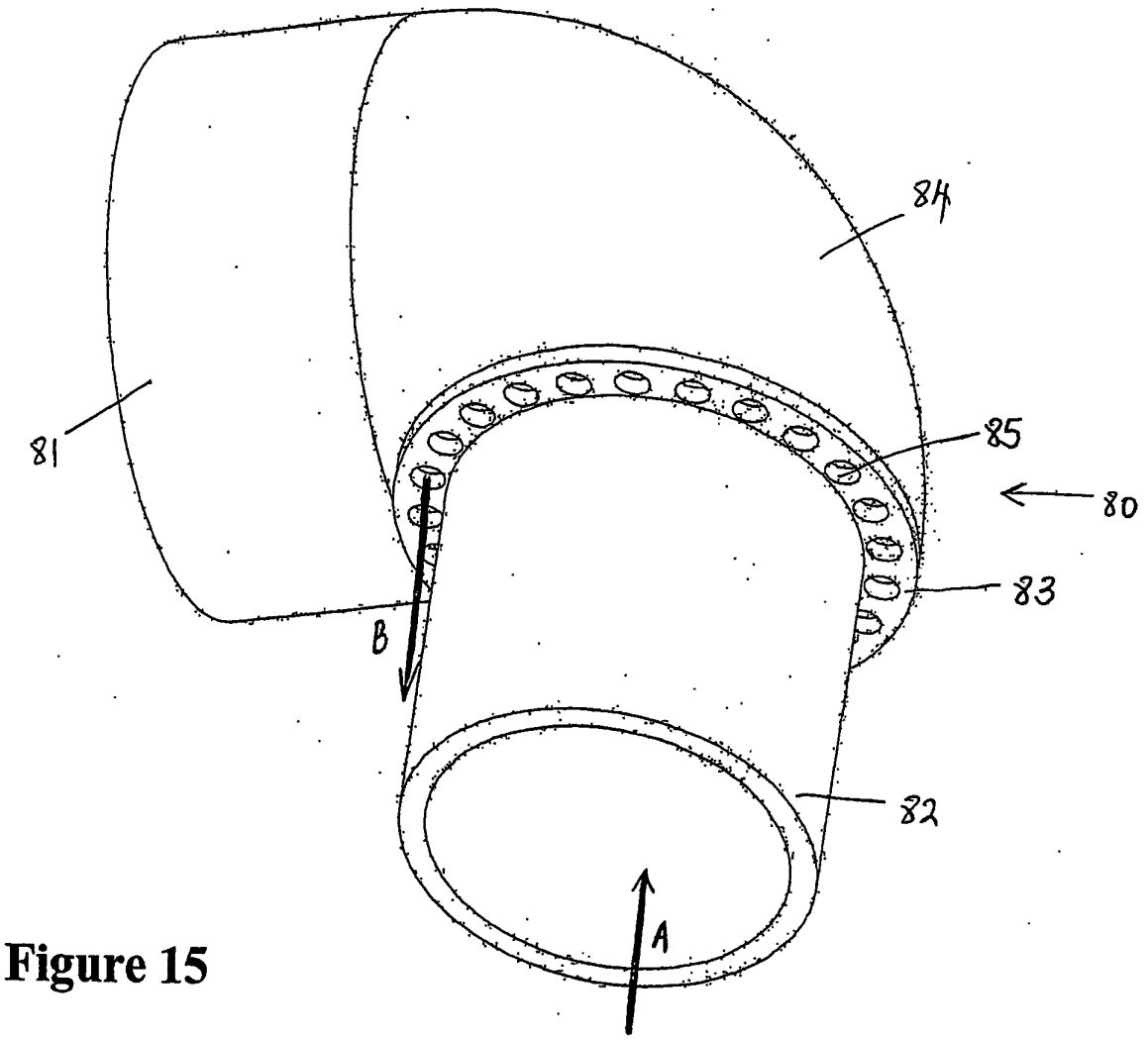

Figure 15

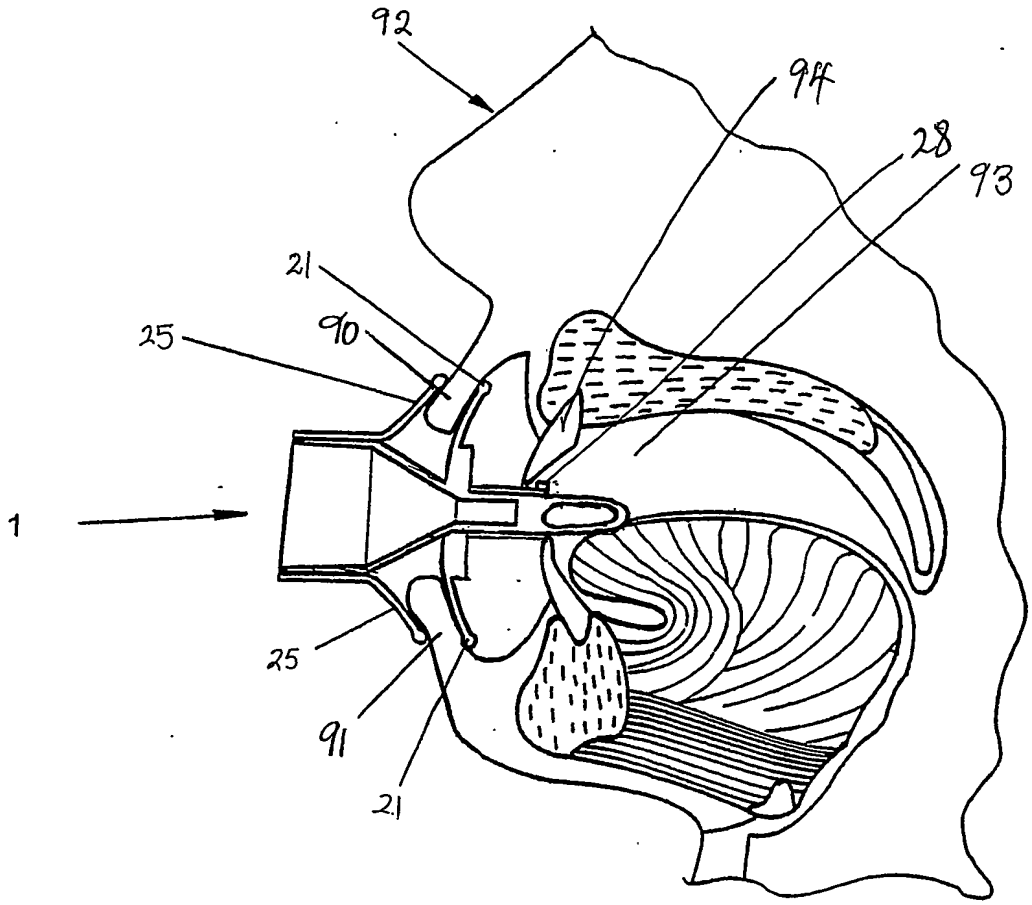

Figure 16

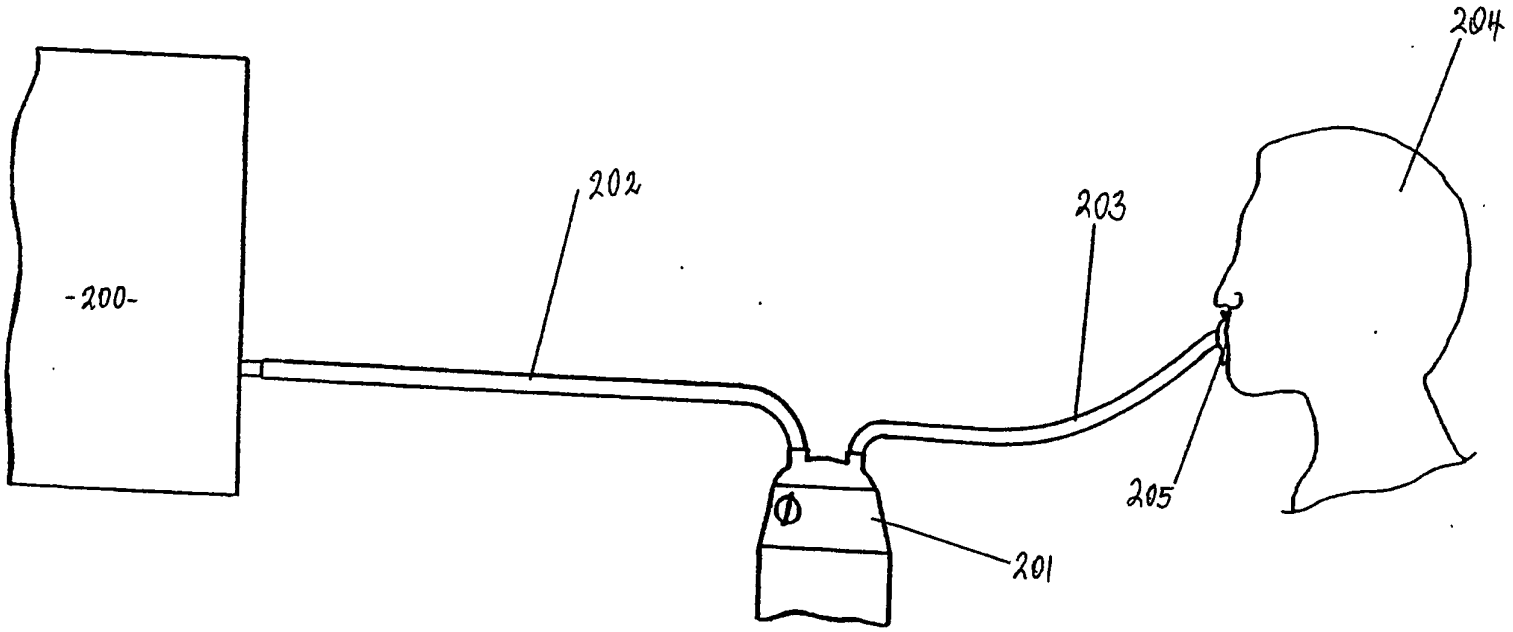

Figure 17

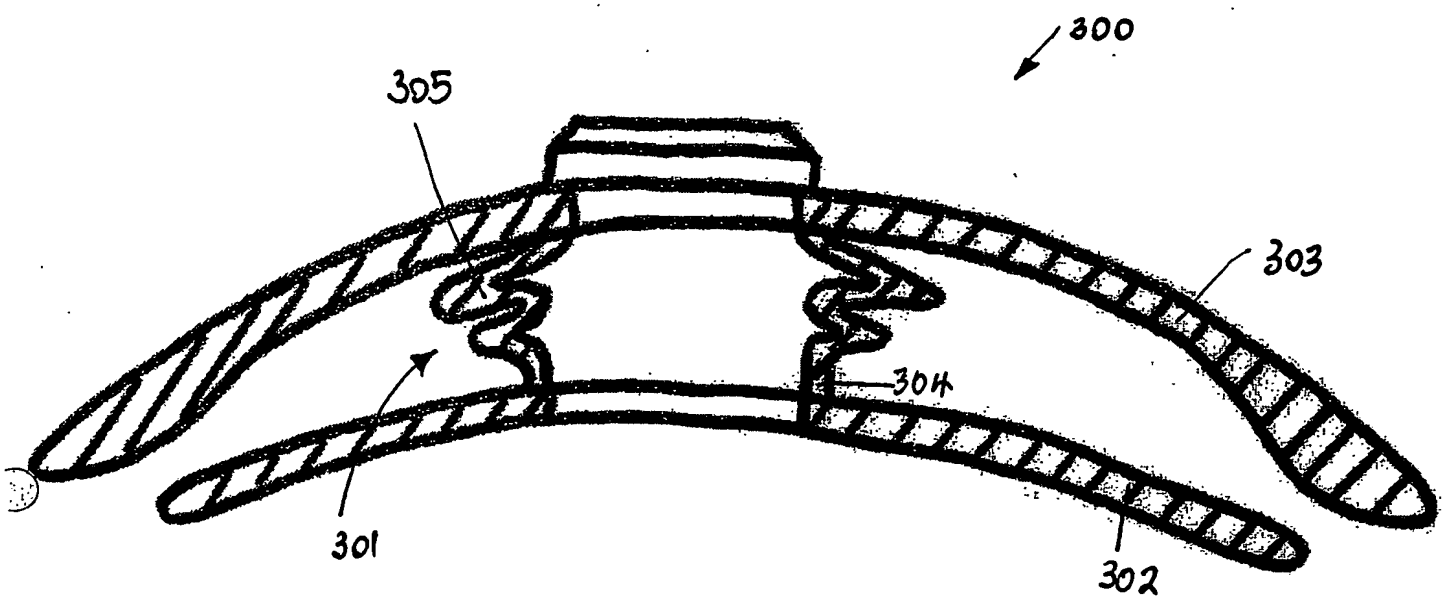

Figure 18

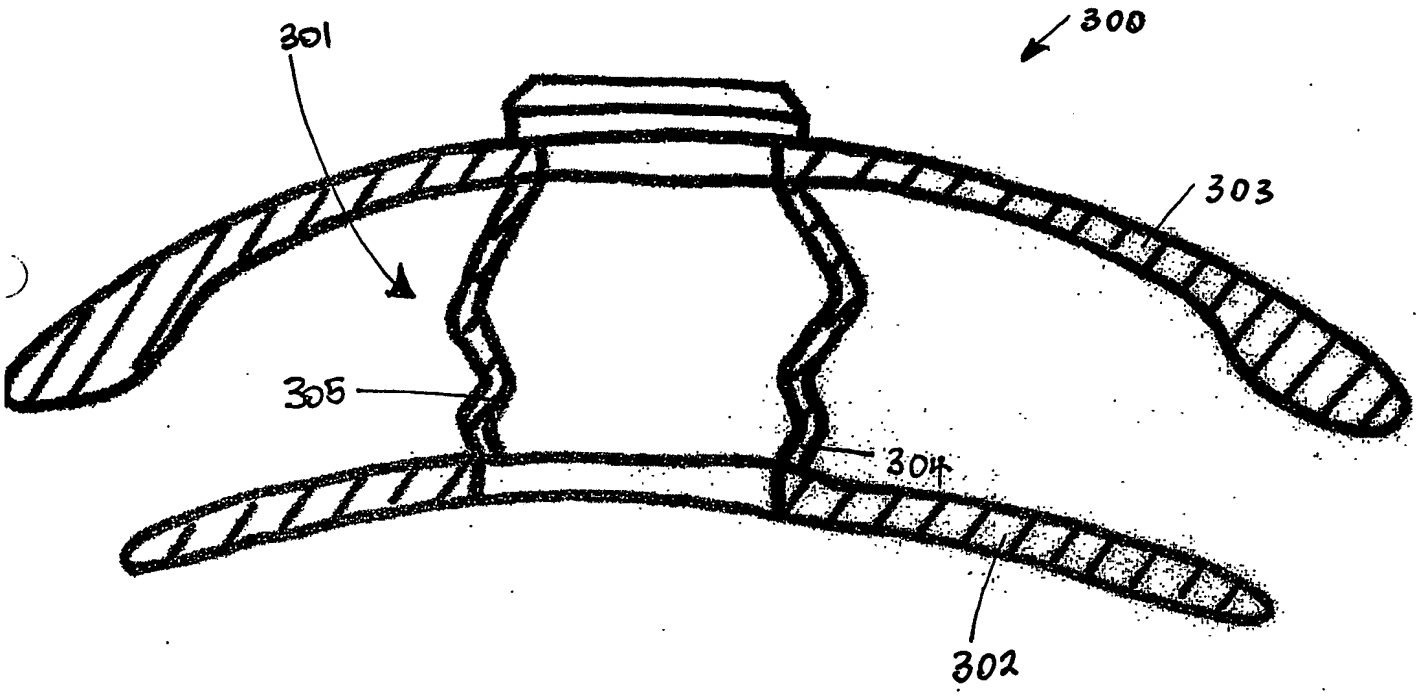

Figure 19

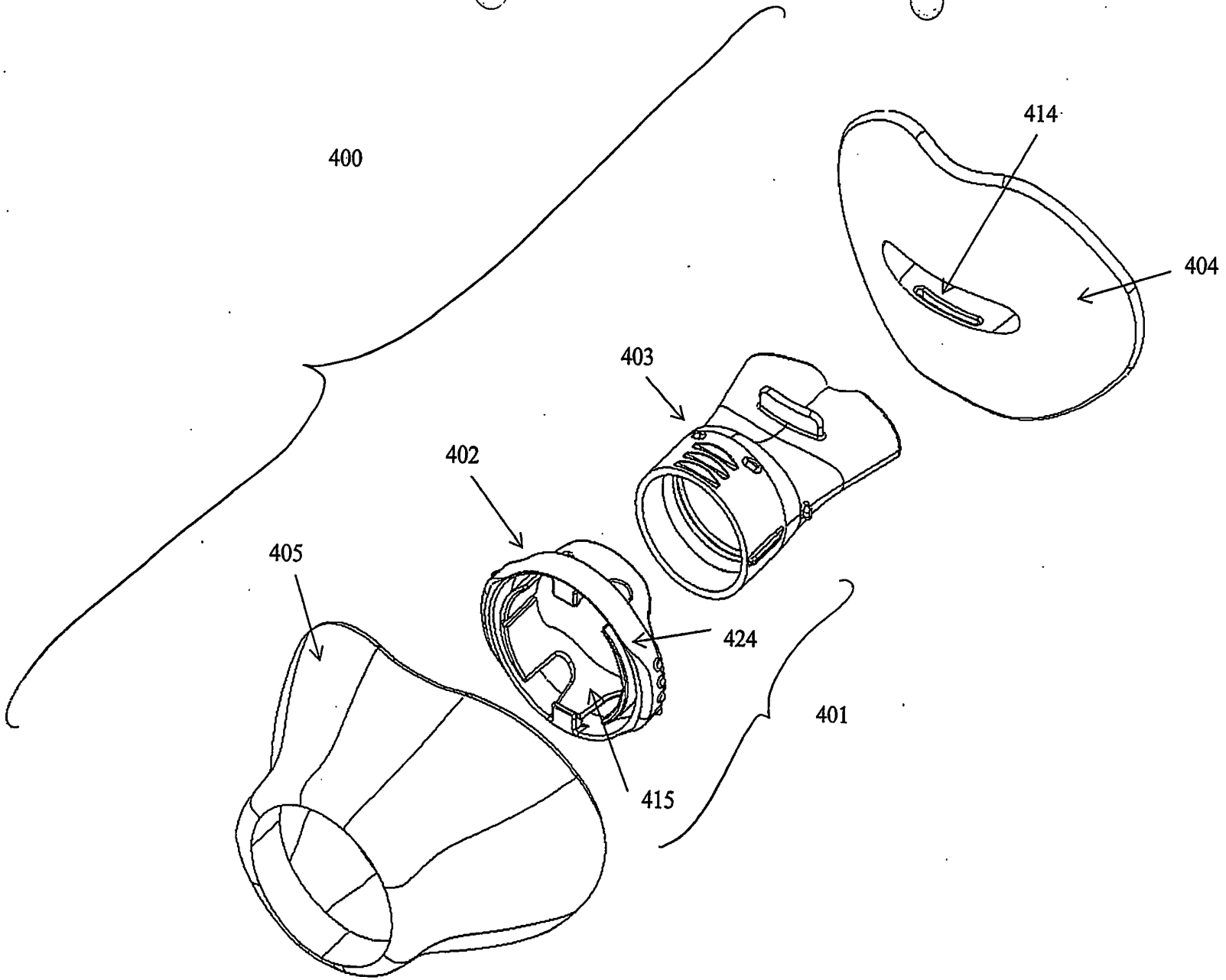

Figure 20

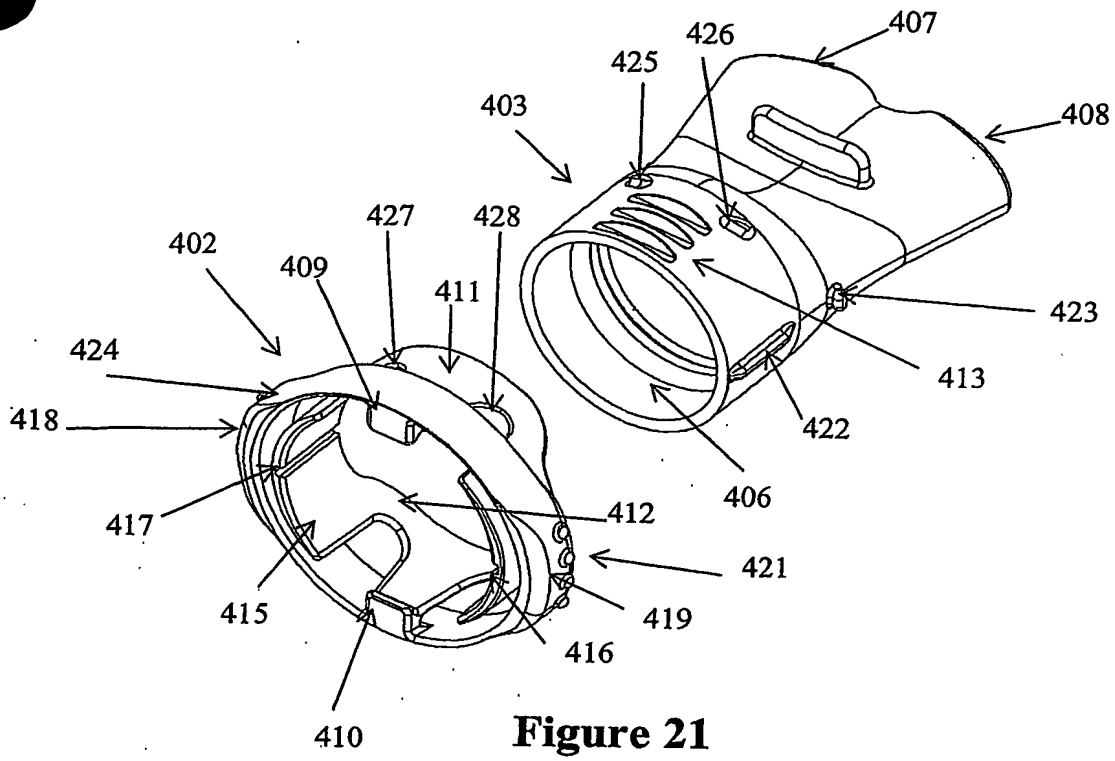

Figure 21

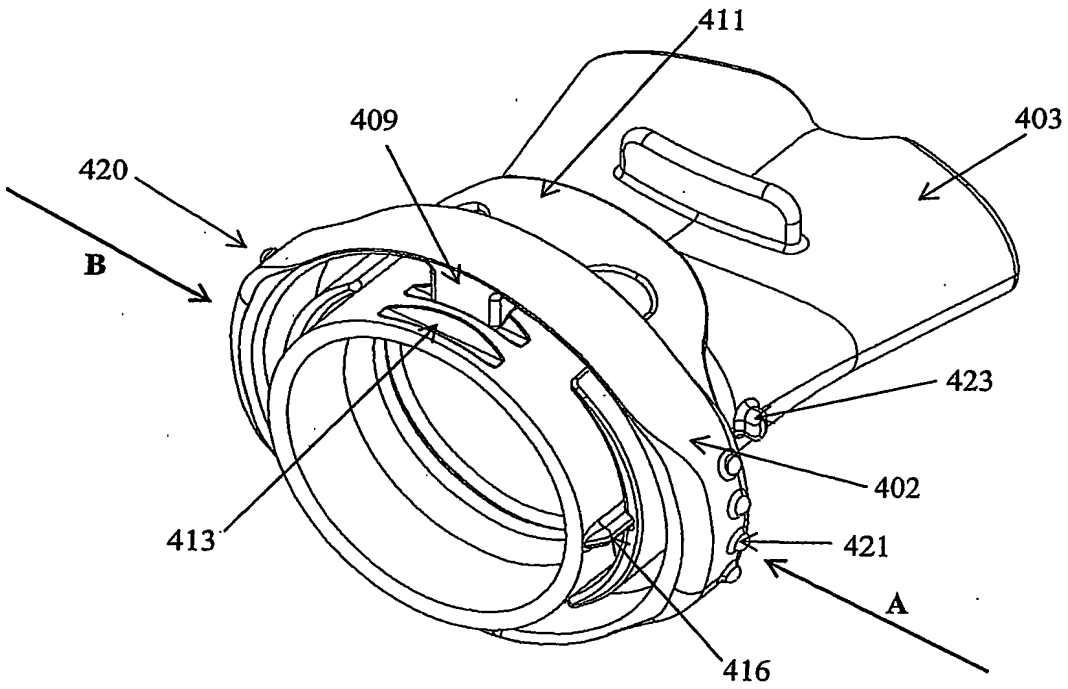

Figure 22

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